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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,732	11/04/98	BARROWS T	09125/001001

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EXAMINER	
RUSSEL, J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/185,732	Applicant(s) T. Barrows et al
	Examiner J. Russel	Group Art Unit 1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 12-26-2000 and 1-19-2001.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-440 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-17, 163-179, 185, 188-193, 195-211, 217, 220-241, 247, 250-267, 271-274, 289, 283-289, and 291-299 is/are allowed.

☒ Claim(s) 18-162, 180-184, 186, 187, 194, 212-216, 218, 219, 242-246, 248, 249, 268-270, 275-279, 281, 282, 290, and 300-440 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 20

☒ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on June 30, 2000; December 26, 2000; and January 22, 2001 have been entered.

2. The consent of assignee to the reissue and the offer to surrender have been received.

The request for transfer of original drawings has been received. This request will be treated as a request to transfer the formal drawings from the original patent file to the reissue application. See MPEP 1413.

The copy of the Certificate of Correction correcting the inventorship of the application has been received.

The corrected copy of the page of the specification corresponding to column 3 of the patent has been received and entered.

The supplemental declaration by Barrows filed October 14, 1999 (a copy of which was attached to the response filed June 30, 2000) in combination with the supplemental reissue oath/declaration filed September 30, 1999 satisfies the requirement under 37 CFR 1.175 for a reissue oath or declaration.

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent

No. 5,583,114 , which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

3. Claims 183, 215, 245, 278, 321, 354, 385, and 419 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: There is no original disclosure of a crosslinking agent concentration as low as 5 mg/ml as recited in claims 183, 215, 245, 278, 321, 354, 385, and 419. The original disclosure (see, e.g., patent claim 1, part (ii), and claim 5) recites a lower limit only as low as 50 mg/ml. It is believed that the lower limit in the new claims may be a misprint.

4. Claims 183, 215, 245, 278, 321, 354, 385, and 419 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. To the extent that the claims contain new matter under 35 U.S.C. 251, they also lack written description in the original disclosure under 35 U.S.C. 112, first paragraph. See the above rejection under 35 U.S.C. 251 set forth in paragraph 3.

5. Claims 18-162 and 300-440 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46

USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

(a) Claims 18-162 are broader in scope than the patented method claims in terms of the protein, protein concentration, crosslinking agent concentration, and burst strength limitation. Claims 300-440 are broader in scope than the patented method claims in terms of protein and burst strength limitation. In particular, the patented method claims require the use of serum albumin, whereas new claims added in this reissue application permit the use of any albumin. The patented method claims require a protein concentration of about 20-60 wt/vol %, whereas new claims added in this reissue application permit the use of any concentration of protein. The patented method claims require a crosslinking agent concentration of about 50-800 mg/ml, whereas new claims added in this reissue application permit the use of any concentration of crosslinking agent. The patented method claims require a burst strength of greater than about 10 mmHg, whereas new claims added in this reissue application permit any burst strength.

(b) These limitations were inserted into the claims eventually allowed in the patent by the amendment filed June 12, 1995 in order to overcome a prior art rejection. Further, the remarks accompanying the amendment filed June 12, 1995 (see, e.g., page 7, line 7, and page 8, lines 2-5) and the remarks filed January 24, 1996 (see, e.g., page 2, line 20, and page 3, lines 2-5) in response to another prior art rejection explicitly refer to the serum albumin and burst strength limitations as helping to distinguish over the prior art on the basis of a patentable difference in terms of composition and characteristics of the composition. In the absence of any other evidence, the making of an amendment to claims in response to prior art rejections permits an inference of surrender. See, e.g., MPEP 1412.02, Example (b). The remarks made by Applicants in conjunction with these amendments (which are in no manner analogous to the "boiler plate" remarks discussed in MPEP 1412.02, Example (A)) are further evidence of surrendered subject matter.

(c) At least one of these instances of surrendered subject matter is present in instant claims 18-162 and 300-440, although not all of the instances of surrendered subject matter occur in every claim. With respect to the protein identity, the independent reissue claims 18, 52, 84, 119, 300, 333, 364, and 398 (which recite "albumin") are now broader in this aspect than originally-presented claim 2 (which recited "serum albumin"). With respect to protein concentration, independent reissue claims 18, 52, 84, and 119 do not recite any protein concentration and thus are as broad in this aspect as the broadest originally-presented claims, which also did not recite a protein concentration. With respect to crosslinking agent concentration, independent reissue

claims 18, 52, 84, and 119 do not recite any crosslinking agent concentration and thus are as broad in this aspect as the broadest originally-presented claims, which also do not recite a crosslinking agent concentration. With respect to burst strength limitation, independent reissue claims 18, 52, 84, 119, 300, 333, 364, and 398 do not recite any burst strength limitation and thus are as broad in this aspect as any of the originally-presented claims (which did not include any burst strength limitation). Broadening the reissue claims with respect to these limitations therefore constitutes the recapture of surrendered subject matter and is improper.

6. Claims 37-41, 43, 44, 71-75, 77, 78, 103-107, 109, 110, 138-142, 144, 145, 180-184, 186, 187, 194, 212-216, 218, 219, 242-246, 248, 249, 268-270, 275-279, 281, 282, 290, 318-322, 324, 325, 332, 351-355, 357, 358, 382-386, 388, 389, 409-411, 416-420, 422, 423, and 431 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 37, line 12, "radical" needs to be changed to "diradical" so that there is antecedent basis in the claim for the phrase "the diradical" at line 14. Analogous changes need to be made to claims 71, 103, and 138 in order to avoid antecedent basis issues. At claim 180, line 10, "and" (second occurrence) should be deleted and at line 12, "or" (first occurrence) should be changed to "and" so that standard Markush terminology is used. Analogous changes need to be made to the Markush terminology of claims 212, 242, 275, 318, 351, 382, and 416. There is no antecedent basis in the claims for the phrase "the pulmonary system" in claims 194, 290, 332 and 431. It is suggested that "the" be changed to "a" in this phrase. Claims 268 and 235; claims 270 and 237;

claims 409 and 375; claims 410 and 376; and claims 411 and 376; are identical in scope. It is believed that this is because the dependencies of claims 268-270 and 409-411 are incorrect.

7. Claims 183, 215, 245, 278, 321, 354, 385, and 419 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 183, 215, 245, 278, 321, 354, 385, and 419 recite a crosslinking agent concentration range with a lower limit of 5 mg/ml. This range is broader than the crosslinking agent concentration range with a lower limit of 50 mg/ml recited in claims 179, 211, 241, 274, 317, 350, 381, and 415, upon which claims 183, 215, 245, 278, 321, 354, 385, and 419 depend.

8. The amendment filed December 26, 2000 contains amendments to claims 1 and 17 that do not comply with 37 CFR 1.121(b) or 1.173(b), which set forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

In particular, at claim 15, line 2, of the amendment filed September 30, 1999, the comma after "formula" has been omitted without the change being marked as required by 37 CFR 1.121(b) or 1.173(b). At claim 1, page 2, line 3, of the amendment filed December 26, 2000, the phrase "d is an integer from 2-10," has been omitted from after the second comma without the change being marked as required by 37 CFR 1.121(b) or 1.173(b). At claim 1, page 2, line 7, a comma has been inserted after "nitrophenyl", the comma after "tresyl" has been changed to

semicolon, and the word "and" which occurred after "tresyl," has been deleted without the changes being marked. At claim 17, line 11, "where" has been changed to "wherein" without the change being marked. At claim 17, page 3 of the amendment, line 4, a comma has been inserted after "nitrophenyl" and the comma after "tresyl" has been changed to a semicolon. At claim 17, page 4 of the amendment filed September 30, 1999, line 2, "diradical" was changed to "radical" without the change being marked as required by 37 CFR 1.121(b). Claims 163, 195, 225, and 258 in the amendment filed contain brackets. However, as these are all new claims added during prosecution of this reissue application, and amendment marking is made with respect to the claims as they occurred when the reissue application was first filed, new claims should be entirely underlined and should not contain bracketing.

9. Applicant's arguments filed January 22, 2001 have been fully considered but they are not persuasive.

As pointed out in paragraph 3 of the Advisory action mailed July 14, 2000, new claims 180, 183, 194, 212, 215, 242, 245, 268-270, 275, 278, 290, 318, 321, 332, 351, 354, 382, 385, 409-411, 416, 419, and 431 require the same corrections that were made to claims 37, 40, 51, 71, 74, 103, 106, 130-132, 138, 141, and 153 in the amendment filed September 30, 1999 in order to avoid the rejections under 35 U.S.C. 112, first and second paragraphs, and 35 U.S.C. 251 (new matter) set forth above.

The rejection of claims 18-162 and 300-440 under 35 U.S.C. 251 as being an improper recapture is maintained for the reasons of record. The rejection has been re-written somewhat to

use an updated form paragraph and to re-organize and supplement the analysis, but the essence of the rejection remains the same as during earlier prosecution of this application.

As stated in Clement, recapture issues arise when the reissue claim is "as broad as or broader than" an aspect germane to a prior art rejection. The identity of the protein is an aspect germane to a prior art rejection because Applicants intentionally amended their claims with respect to the proteins being claimed and explicitly argued that the identity of the protein distinguished over the prior art. Now in the reissue claims, the protein limitation has been expanded with respect to the patented claims and now recites "albumin protein". This limitation is "as broad as or broader than" the protein limitation in claim 2 (i.e. "serum albumin") which was originally filed in the parent application which issued as the patent. Claim 2 was not "simply incorporated" into independent claim 1 during prosecution of the parent application - the limitations of claims 3 and 7 were also incorporated into independent claim 1, as were a new crosslinking agent concentration, a new functional limitation ("is initially liquid..."), and a new burst strength range. Whether the comparison is with "an aspect germane to a prior art rejection" as stated in Clement, or with a canceled or amended claim as stated by Applicants, Applicants' broadening of the four limitations identified in the rejection constitute recapture of surrendered subject matter.

Applicants argue that surrender is precedent to application of the recapture rule. The examiner would like to point out that the section of the advisory action quoted by Applicants in no way contradicts this argument. The quotation from the advisory action only states that

surrender and recapture are separate issues. The recapture rejections both as originally stated and as re-written above address both surrender and recapture.

The examiner's position is that the presence of surrender is apparent from the prosecution history as a whole. With respect to the four limitations identified in the rejection, the limitations were inserted into the claims in response to prior art rejections by the examiner, and the limitations were argued by Applicants as distinguishing over the applied prior art. The case law and MPEP permit a presumption of surrender when a limitation is inserted into a claim in response to a prior art rejection, even in the absence of any arguments by Applicants or comments by the examiner concerning the inserted limitation. See, e.g., MPEP 1412.02, Example (b). Applicants' arguments made in conjunction with and in reference to the amendments do not detract from but rather support the presumption of surrender. Insofar as the MPEP discounts "boiler plate" distinctions over the prior art as establishing recapture (see Applicants' citation at page 4 of the response), Applicants' arguments during prosecution of the parent application concerning the new claim limitations (see, e.g., Applicants' quotations of these arguments at pages 3-4 of the response) are in no way comparable to the MPEP's example of a "boiler plate" sentence (i.e., "In closing, it is argued that the limitations of claims 1-7 distinguishes the claims from the teachings of the prior art, and claims 1-7 are thus patentable.).

The examiner does not accept Applicants' argument that amending an independent claim does not substantively amend a dependent claim. "A claim in dependent form shall be construed

to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. 112, fourth paragraph.

Concerning Applicants' argument at page 5, first paragraph, of the response, the examiner is unable to affirm or deny this "proposed rule" because of uncertainty as to what Applicants mean by "related to an amendment in light of a prior art rejection". The examiner agrees that if an amendment is made by Applicants during original prosecution in response to a prior art rejection in an attempt to distinguish over the applied prior art, then surrender exists and the recapture rule prevents broadening claims in a reissue application with respect to the surrendered subject matter. As far as the examiner can determine (and note that the examiner does not have the authority to speak on behalf of the PTO on the issue requested by Applicants), the MPEP's section concerning recapture merely quotes what the courts have stated in their decisions concerning recapture, and the MPEP therefore is correct in its discussion of the issue. While Applicants' "albumin protein" limitations are narrower than the broadest originally-presented claims in the parent application, the new claim limitations still do not avoid the recapture of surrendered subject matter with respect to protein concentration, crosslinking agent concentration, and burst strength (the reissue claims are as broad as the broadest originally-presented claims in the parent application with respect to this surrendered subject matter). In any event, as discussed above, Applicants' "albumin protein" limitations are broader in scope than originally presented claim 2's "serum albumin", and constitute recapture of subject matter broader than the serum albumin to which the claims were limited during prosecution of the parent application.

In the personal interview of February 22, 2001, Applicants requested that the examiner specifically consider and comment on Ball and Richman, copies of which were attached to Applicants' response filed January 22, 2001. Applicants' position was that these cases supported the proposition that recapture does not prevent reissue claims directed to subject matter intermediate in scope between the patented claims and the broadest claims presented during prosecution of the application which resulted in the patent, even where the subject matter of the reissue claims is broadened in an aspect related to an amendment made in response to a prior art rejection.

Clement directly answers this query. In Clement, the appellant argued that for purposes of determining surrender and recapture, the reissue claims should be compared only with the broadest originally-presented claims (see page 1471, column 2, first full paragraph), and the court refused to make this comparison (see the paragraph bridging pages 1471 and 1472). Clement distinguished Ball on the basis that in Ball, the broadened claim limitations concerned aspects unrelated to the rejections (see page 1470, column 2, first full paragraph). This is not the situation in the instant reissue application, where the broadened claim limitations do concern aspects related to prior art rejections made in the parent application. See also Clement's discussion of Ball at page 1471, paragraph bridging columns 1 and 2, where the decision in Ball is limited to its facts. Accordingly, Ball does not support Applicants' position. Richman is also distinguishable from the instant application in that in Richman, each of the appealed reissue claims were more restrictive in at least one significant respect than the canceled claims (see page 276,

column 1, second full paragraph). Richman's dicta in the paragraph bridging pages 274 and 275 can not be relied upon to distinguish Clement when the instant fact situation is more directly addressed in Clement.

10. After the corrections specified in paragraph 8 above are made, claims 1-17 will be allowed. Claims 163-179, 185, 188-193, 195-211, 217, 220-241, 247, 250-267, 271-274, 280, 283-289, and 291-299 are allowed. Claims 180-184, 186, 187, 194, 212-216, 218, 219, 242-246, 248 249, 268-270, 275-279, 281, 282, and 290 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 and under 35 U.S.C. 251 (new matter) and the claim objections set forth in this Office action.

11. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7401 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1653

JRussel
February 26, 2001